

APR 18 1996

Mr. A. P. Power  
Nutritional Life Support Systems  
10020 Pioneer Boulevard #105  
Santa Fe Springs, California 90670

Dear Mr. Power:

This is in response to your letters of January 9 and February 20, 1996 making a submission to the Food and Drug Administration (FDA) pursuant to section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the act). Your submission states that you are making the following statement of nutritional support for the product "Lung Clear:"

Special herbs in this formula have been used traditionally in the Orient to help expel mucus and clear infections in the lungs, throat and sinuses.

We would point out that section 403(r)(6) of the act makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statement that you are making for "Lung Clear" suggests that this product is intended to treat or mitigate disease, in that it evidences that the product is intended to "help expel mucus and clear infections in the lungs, throat and sinuses." Therefore, this claim does not meet the requirements of section 403(r)(6) of the act. This claim suggests that this product is intended for other than food use within the meaning of section 201(g) of the act and that it is subject to regulation under the drug provisions of the act. Furthermore, it appears that this product is intended for drug use within the meaning of section 201(g)(1)(B) of the act.

If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

Sincerely yours,

John Gordon  
Acting Director,  
Division of Programs and  
Enforcement Policy  
Office of Special Nutritionals  
Center for Food Safety  
and Applied Nutrition

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